

AF/1621^{17W}

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT Application of
Berscheid, et. al.

Group Art Unit: 1621

Application Serial No. 08/860,007

Examiner: Shippen

Filed: August 4, 1997

For: BIOCIDAL ALCOHOLS, THEIR PRODUCTION AND THEIR USE

* * * *

December 17, 2004

REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants submit herewith a Reply Brief in triplicate in accordance with 37 C.F.R. § 1.193(b).

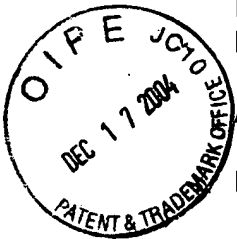
Appellants submit that the claimed invention is patentable over the cited references for the many reasons advanced in the Appeal Brief. Appellants provide the following additional remarks in response the Examiner's Answer.

Appellants are frustrated by the Examiner's continued refusal to consider the substantial experimental evidence of record, give proper weight to a previous favorable examination, and his blatant disregard for established patent law and rules even after being admonished by the Board in its January 29, 2003 Decision, as discussed below in reference to each of the rejections of record.

Claims 8, 14, 16-18 and 21-25 are patentable under 35 U.S.C. § 103 over U.S. Patent No. 4,110,430 (Hopp) for the reasons advanced in Appellant's Brief and for the following reasons.

In his Answer, the Examiner states that:

It is noted that in their reply brief of Paper No. 22 Appellants submitted additional evidence in the form of screening tests and a reference



written in a foreign language. The screening test data is not presented in proper form, see 37 CFR 1.132. As such it has been given little weight in consideration of the patentability of the instant claims. The reference is not in English and a translation was not provided. As such the reference has not been considered. (See the last paragraph on page 12 of the Examiner's Answer.)

Appellants timely submitted the screening tests in a proper Declaration, in accordance with 37 CFR 1.132, with their September 23, 2003 Response. Another copy of that Rule 132 Declaration was filed with Appellants' October 14, 2003 Response. Both Responses were entered in Examiner's paper no. 30. That Rule 132 Declaration specifically states that the declarant "performed or supervised the experiments in the paper entitled "Results of Screening Biocidal Alcohols" filed in the present application on July 17, 2000," which the Examiner refers to above as Paper no 22. See page 18 of Appellants' September 23, 2003 Response, which specifically refers to the Rule 132 Declaration containing the screening tests. Thus, the Examiner's position that the experimental results are not properly submitted is simply not true. Appellants once again request proper consideration of that compelling evidence.

Appellants also timely submitted an English translation of the reference referred to by the Examiner with their September 23, 2003 response. See page 23 of Appellants' September 23, 2003 Response, which specifically states that "Attached is a translation of R.Berschied, M. Nieger, F. Vogtle, *Chem. Ber.* 1992, 125, 2539-2552." Since the translation was timely filed, Appellants do not understand the Examiner's refusal to consider this evidence.

On page 13 of the Examiner's Answer, the Examiner states:

Applicants assert that the experimental evidence disclosed in the specification demonstrates unexpected advantages of the claimed compounds compared to the compounds of HOPP. It is unclear what evidence in the specification applicants are relying upon and they do not point to any specific evidence. It is noted that in Paper No. 13 it was pointed out to applicants that the tables set forth in the specification have been carefully considered by not found persuasive of patentability. The Tables do not make any direct comparison of a prior art compound with the structurally closest claimed compounds. As such there is no evidence that the claimed compounds possess unexpectedly superior properties or properties different from the prior

art. Applicants simply do not address this point. It is of no moment that the prior art does not teach the same activity or utility for the prior art compounds as described by applicants. The skilled artisan need possess only some motivation to modify the prior art compound, and that such motivation need not coincide with one driving an applicant. ..." (emphasis added)

A quick reading of Appellants' Brief proves this statement by the Examiner to be flat out wrong. See page 19 of Appellants' Brief, which states:

Even if the Examiner has provided a *prima facie* case, the experimental evidence of record rebuts any such *prima facie* case of obviousness. Claims 8, 14, 16-18 and 21-25 recite novel compounds and compositions which are not disclosed in Hopp. The experimental evidence disclosed in the present specification demonstrates the unexpected advantages of the claimed compounds compared to those disclosed in Hopp. Hopp only discloses that their compounds have a microbicide effect on staphylococcus epidermis and aureus, and candida albicans. In contrast, the claimed compounds and compositions exhibit an unexpected microbicide effect against e-coli (Tables on pages 19, 21, 25, and 27 of the present application), as well as unexpected **anti-fungal properties** (Tables on pages 23 and 24 of the present application). Hopp does not teach or suggest that the claimed compounds have anti-fungal properties or microbicide properties against e-coli and therefore cannot make obvious the compounds and compositions recited in claims 8, 14, 16-18 and 21-25. (emphasis in original)

As can be clearly seen from this statement, Appellants provided specific cites to the specification as to what experimental evidence they were referring to and also pointed out different properties not disclosed in Hopp. Once again, Appellants are at a loss as to why the Examiner simply ignores this experimental evidence.

Appellants are confused as to why the Examiner would allege that no Rule 132 Declaration was submitted and then two pages later argue that the Rule 132 Declaration is not persuasive for the following reasons:

Applicants assert that the declaration filed under 37 CFR 1.132 on September 23, 2003 shows that lipophily and topology play a major role in the biocidal activity of the instant compounds. The declaration has been carefully considered but not found persuasive of patentability. First, whether or not this is the case it does not demonstrate that the claimed compounds possess unexpectedly superior properties or properties different from the prior art. It is

particularly noted that as to all of the compounds tested in the declaration, there is no direct comparison of a prior art compound with the structurally similar closest claimed compounds. As such there is no evidence that the claimed compounds possess unexpectedly superior properties or properties different from the prior art. (emphasis added.)

Appellants pointed out very clearly that Hopp does not teach compounds having anti-fungal properties nor microbicide effect against e-coli. These properties are different from Hopp. Appellants' Rule 132 Declaration explains why the properties of the claimed invention are different from Hopp's compounds based on mechanisms that are more modern and accurate than the outdated theories of positional isomerism and homology relied upon by the Examiner, as shown by Appellants' extensive argumentation in their Briefs filed April 28th, 2000 and July 17th, 2000, as well as Appellants' present Brief filed September 23, 2003 starting on page 17. The modern approach is based on "famous" compounds like lactic acid and Thalidomide (stereoisomerism), as well as retinal (photo-isomerization) and new results including American Nobel Price Awards for so called "buckyballs," which are only a few examples of the huge number of known compounds that do not follow the simple theory of "positional isomerism" and "homology" followed by the Examiner. While this new modern approach explains why the properties of isomers and homologs are different, it does not explain the specific unexpected properties, anti-fungal properties and microbicide effect against e-coli, of the claimed compounds. The testing of Hopps' compounds is expensive and Appellants know of no law that requires direct testing when the properties are already shown to be different, nor any law which allows the Examiner to simply ignore Appellants' extensive experimental evidence of record.

Appellants respectfully submit that the Examiner has not provided a *prima facie* case of obviousness and even if a *prima facie* case has been provided the claimed invention is not obvious from Hopp in view of the extensive experimental evidence of record as discussed in Appellants' Brief and herein.

Claims 8, 13, 14, 16-18, 21-25 and 33-35 are patentable under 35 U.S.C. § 103 over U.S. Patent 4,321,257 (Sipos) for the reasons advanced in Appellants Brief and for the following reasons.

Appellants respectfully submit that the Examiner misstates the teachings of Sipos by continuously arguing that the “**potentiators**” are “active agents.” The numerous compounds of Sipos cited by the Examiner on pages 14-15 and pages 19-20 of his Answer are all “potentiators” as taught by Sipos. Sipos teaches that “a broad group of known antimicrobial agents have increased activity, either in terms of spectrum, killing power, or both when used in combination with the potentiating agents of this invention.” See column 1, lines 20-25 of Sipos. See also columns 3 and 4 of Sipos, which clearly distinguishes “antimicrobial agents” from “potentiators.” In particular, Sipos teaches that “the term ‘potentiator’ is meant to indicate on the one hand, that the compound enhances the activity of an antimicrobial agent over what it ordinarily would be if otherwise used alone.” See column 3 lines 15-20. The antimicrobial agents are active agents, not the potentiators. Sipos clearly teaches away from the claimed invention by teaching that the potentiators are not active agents.

The Examiner simply flips Sipos on its head by now arguing that Sipos teaches that the potentiators are active agents. See the bottom of page 15 in the Examiner’s Answer, in which the Examiner states that “[t]hese active agents are disclosed in the reference as being useful in antimicrobial compositions.” See also page 20 of the Examiner’s Answer in which he states “[t]he structural relationship of these claimed active agents compared to the SIPOS active agents is characterized as ‘positional isomers’.” See further page 22 of the Examiner’s Answer in which the Examiner states that “one would expect to obtain additional active agents having the prior art use by such a modification of the prior art.” These statements simply are not true. The actual active agents in Sipos (conventional microbicides) are not cited by the Examiner since they are structurally far removed from the presently claimed active agents. Sipos only teaches adding potentiators to these known antimicrobial compounds. There simply is no teaching in Sipos or any of the cited references to

use the presently claimed compounds as active agents, not merely as potentiators. For this reason alone, the Section 103 rejection should be withdrawn.

On page 26 of his Answer, the Examiner once again misstates the record by stating that:

It is noted that in their reply brief of Paper No. 22 Appellants submitted additional evidence in the form of screening tests and a reference written in a foreign language. The screening test data is not presented in proper form, see 37 CFR 1.132. As such it has been given little weight in consideration of the patentability of the instant claims. The reference is not in English and a translation was not provided. As such the reference has not been considered. (See the last paragraph on page 26 of the Examiner's Answer.)

As discussed above, Appellants timely submitted the screening tests in a proper Declaration, in accordance with 37 CFR 1.132, with their September 23, 2003 Response. Another copy of that Rule 132 Declaration was filed with Appellants' October 14, 2003 Response. Both Responses were entered in Examiner's paper no. 30. That Rule 132 Declaration specifically states that the declarant "performed or supervised the experiments in the paper entitled "Results of Screening Biocidal Alcohols" filed in the present application on July 17, 2000," which the Examiner refers to above as Paper no. 22 (Appellants' first Reply Brief of July 17, 2000). See page 18 of Appellants' September 23, 2003 Response, which specifically refers to the Rule 132 Declaration containing the screening tests. Thus, the Examiner's position that the experimental results are not properly submitted is simply not true. Appellants once again request proper consideration of that compelling evidence.

Appellants also timely submitted an English translation of the reference referred to by the Examiner with their September 23, 2003 response. See page 23 of Appellants' September 23, 2003 Response, which specifically states that "Attached is a translation of R.Berschied, M. Nieger, F. Vogtle, *Chem. Ber.* 1992, 125, 2539-2552." Since the translation was timely filed, Appellants do not understand the Examiner's refusal to consider this evidence.

In the first full paragraph on page 27 of his Answer, the Examiner states that:

Applicants point to the fact that the reference does not teach applicant's properties. It is of no moment that the prior art does not

teach the same activity or utility for the prior art compounds as that described by applicants. (emphasis added)

One paragraph later, the Examiner argues that "there is no evidence that the claimed compounds possess unexpectedly superior properties or properties different from the prior art compounds." (emphasis added) See the sentence bridging pages 27 and 28 of the Examiner's Answer. On the one hand the Examiner refuses to consider Appellants' experimental evidence showing different and unexpected properties (anti-fungal properties and microbial effect on e-coli) because it "makes no moment" and on the other hand refuses to withdraw the rejection because Appellants did not show how the properties are different from the prior art. This circular argumentation flies in the face of established patent laws and rules governing how experimental evidence is submitted and considered to rebut a Section 103 rejection. There is no law or rule Appellants are aware of that requires them to test a "potentiator" of Sipos to see if can now be used as an "active agent."

On page 28 of the Examiner's Answer, the Examiner states:

Applicant's discussion of the "Chem. Ber., Vol 125, pp. 2539-2552 (1992)" article is noted but not found persuasive. This article has been considered only to the extent of the translation provided by applicants in their response. First, there is not correlation to the steric effect shown in the dye molecules in the reference to the instant compounds. It is noted that the compounds shown in the article are structurally quite remote from the compounds at issue here. The fact that there exist other nonrelated compounds that may have unexpected properties, does not show that the instant compounds possess unexpected properties.

Appellants are quite surprised that the Examiner now admits that a translation of the article was actually submitted by Appellants after arguing twice on pages 12 and 26 of his Answer that the translation was not submitted. This article was not submitted to show "that the instant compounds possess unexpected properties," but rather to show that the Examiner's reliance upon "position isomerism" to support his prima case is untenable. Appellants specifically stated:

The translation of R. Berscheid, M. Nieger, F. Vögtle, *Chem. Ber.* **1992**, 125, 2539-2552, discloses a triply-bridged dye molecule, its

synthesis and solvatochromic and halochromic effects to different isomeric structures in table 7 (page 2542). For example 1,2-dimethylbenzene exhibited a significant shift in UV spectra while 1,4-dimethylbenzene does not. This effect is explained by sterical reasons and the topology of the molecule. The 1,2-dimethylbenzene fits to the host structure while the 1,4-isomer does not. This article demonstrates that the simple view of isomers having similar activity is not always true. ((emphasis added) See page 25, second to last paragraph in Appellants' Brief.)

The Examiner simply brushes this argument aside. Appellants request full consideration of their argument that positional isomerism is not sufficient to provide a *prima facie* case of obviousness. Appellants have pointed out other extensive experimental evidence demonstrating the unexpected properties of the claimed invention, which the Examiner also fails to address.

In view of the many differences between the claimed invention and Sipos, the lack of a *prima facie* case of obviousness, and the unexpected advantages of the claimed invention, withdrawal of the Section 103 rejection is respectfully requested.

Claim 26 is patentable under 35 U.S.C. § 103 over U.S. Patent 4,968,668 (Hafner) in view of Vogel, "A Textbook of Practical Organic Chemistry

On page 34 of the Examiner's Answer, the Examiner accuses Appellants of "seriously mispresent[ing] the examiner's position as to the disclosure of Hafner (bottom portion of page 26 of appellant's brief)." The specific language referred to by the Examiner is:

The Examiner admits that Hafner uses different reactants and, thus, forms different products than those presently claimed. The Examiner merely argues that the use of a new starting material in an otherwise old process is considered obvious and improperly cites cases as the only basis for the rejection. Appellants point out the claimed invention is a novel process and novel starting materials, not merely new starting materials in an old process as alleged by the Examiner. (See bottom portion of page 26 of Appellant's August 3, 2004)

Appellants' take exception to the Examiner's use of "serious misrepresent" as this infers that Appellants had some intent to deceive the Board. Appellants had no intent to deceive the Board or to misrepresent the Examiner's position. Appellants relied upon the Examiners statement that "Hafner teaches an analogous process that differs from the claimed process in that the prior art does not recite step (a) and some of the reactants differ as to the substituents present. (emphasis added) See page 29, first full paragraph, and page 30, step B, of the Office Action dated March 24, 2004. Appellants understood these statements by the Examiner to mean that Hafner uses different starting materials. In view of the Examiner's overly harsh criticism and reconsideration of the amendment of claim 26 to remove reference to $n=2$, Appellants now withdraw this argument. However, Appellants still submit that claim 26 recites a novel process using novel starting materials.

The Examiner simply ignores the extensive experimental evidence of record rebutting the prior art rejection of claim 26. The Examiner states:

Appellant's assertion that the products possess unexpected properties is without merit. First, the claims read on products identical to those obtained by HAFNER. Second, as has been pointed out in the rejection, the various evidence relied upon by appellants for unexpected properties is lacking.

The Examiner improperly brushes aside Appellant's experimental results and arguments based on the premise that the products of the claimed method are identical to Hafner. Even if the products were identical as alleged by the Examiner, such is a not a valid reason to ignore the experimental evidence of record used to rebut a Section 103 rejection.

Furthermore, the Examiner falsely alleges that he "pointed out in the rejection" how Appellants' evidence is lacking. Looking at pages 28-31 of the Examiner's Answer, where his "rejection" is located, Appellants fail to see where the Examiner even mentions the unexpected results. Looking further back at the Examiner's Final Office Action of January 14, 2004, at pages 5-6, the Examiner

points out nothing regarding Appellants' unexpected results. Appellants specifically pointed out to the Examiner that:

... the compounds formed by the claimed method exhibit antimicrobial, disinfectant, deodorant, antimycotic or preservative properties. Hafner only discloses that the alcohols disclosed therein provide fragrance properties. Vogel also does not teach or suggest a method of forming compounds that are suitable for use as antimicrobial, disinfectant, deodorant, antimycotic or preservative agents." (See page 28 of Appellants' Appeal Brief.)

The Examiner simply ignores this experimental evidence in disregard of well established patent rules. Appellants request full consideration of the experimental evidence of record.

In view of the lack of motivation to combine the cited references, the many differences between the claimed invention and the cited references, and the unexpected advantages of the claimed invention, withdrawal of the Section 103 rejection is respectfully requested.

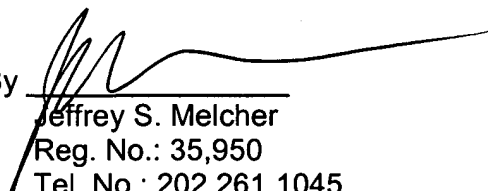
Conclusion

Appellants are surprised that Supervisory Patent Examiner Johann R. Richter and Primary Examiner Samuel Barts would be parties to the hostile prosecution of this application conducted by Examiner Michael Shippen. (See page 35 of the Examiner's Answer.) In view of Examiner Shippen's harsh criticisms of Appellants' Brief, Appellants feel compelled to point out six blatant misstatements—Appellants are loath to use the term misrepresentation—of the record, which are listed in an attachment to this Reply Brief.

For all of the reasons advanced in Appellant's Brief On Appeal and for the reasons advanced above, it is submitted that the present invention as recited in each of Appellant's claims is in proper condition for allowance. Accordingly, Appellants respectfully request that the Board allow claims 8, 13, 14, 16-18, 21-26 and 33-35 over the cited references.

Respectfully submitted,

Manelli Denison & Selter, PLLC

By 
Jeffrey S. Melcher
Reg. No.: 35,950
Tel. No.: 202.261.1045
Fax. No.: 202.887.0336

2000 M Street, N.W.
7th Floor
Washington, D.C. 20036-3307

ATTACHMENT

1. The Examiner misstates on pages 12 and 26 of his Answer that no Rule 132 Declaration was submitted for the screening results submitted on July 17, 2000. Appellants timely submitted such a Rule 132 Declaration twice, with their September 23, 2003 and October 14, 2003 Responses, both entered by the Examiner in paper no. 30. The Rule 132 Declaration specifically referred to the July 17, 2000 submission.
2. The Examiner misstates on pages 12 and 26 of his Answer that no translation of R. Berscheid, M. Nieger, F. Vögtle, *Chem. Ber.* **1992**, 125, 2539-2552 was submitted. Appellants submitted a translation with their September 23, 2003 Response entered by the Examiner in paper no. 30.
3. The Examiner misstates on pages 14-15 and pages 19-20 of his Answer that the "potentiators" of Sipos are "active agents." Sipos specifically teaches that the potentiators are not active microbicides, but are only combined with active microbicides to enhance their activity.
4. The Examiner misstates on page 13 of his Answer that "it is unclear what evidence in the specification applicants are relying upon and they do not point to any specific evidence." On page 19 of their Appeal Brief, Appellants specifically pointed out by page number the specific experimental evidence they were referring to by stating "(Tables on pages 19, 21, 25 and 27 of the present specification), as well as unexpected anti-fungal properties (Tables on page 23 and 24 of the present specification)."
5. The Examiner misstates on page 13 of his Answer that "there is no evidence that the claimed compounds possess ... properties different from the prior art." On page 19 of their Appeal Brief, Appellants specifically pointed out that the prior art does not teach or suggest the unexpected properties of anti-fungal properties and microbicide effect against e-coli.
6. The Examiner misstates on page 6 of his January 14, 2004, final Office Action that "when the present examiner was assigned the instant application to be examined, there were no search notes present in the file wrapper. As such there was in fact no search to give full faith and credit to. Applicants should further note, the instant examiner is a primary examiner..." As a primary Examiner, present Examiner Shippen should have known that search results are demonstrated by a Form PTO-892, which original Examiner Puttlitz clearly had attached to his October 3, 1997 Office Action indicating allowability of the present claimed subject matter. See also the Form PTO-1449 attached to that Office Action and initialed by the original Examiner, which contained reference to Hopp.